K130638

PHILIPS

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510(k) Summary

This 510(k) summary is prepared in accordance with 21 CFR 807.92.

JUN 28 2013

Date Prepared:	June 10, 2013
Manufacturer:	Philips Medical Systems Netherlands B.V. Veenpluis 4-6 5684-PC, Best, The Netherlands
Contact:	Klien van Dam, PhD
Device Trade Name:	AlluraClarity Xper FD Series X-ray System
Regulation Number:	Regulation Number: 21 CFR 892.1650
Regulation Name:	Image Intensified fluoroscopic x-ray system
Regulatory Class:	Class II
Product Code:	OWB
Predicate Devices:	Allura Xper FD OR Tables Series (K102005) Allura Xper FD10 (K041949) Allura Xper FD20 (K033737)
Device Description:	The AlluraClarity Xper FD Series X-Ray System (AlluraClarity system) is a modular angiographic X-ray system, based on a set of components that can be combined into different single and biplane configurations to provide specialized angiography. Combined with a qualified, compatible OR table, the AlluraClarity system can also be used for imaging in the Hybrid OR. The AlluraClarity system is provided with ClarityIQ technology, which utilizes the advanced XRES4 noise reduction algorithms to reduce quantum noise in X-ray images.
Indications for Use:	The AlluraClarity Xper FD Series X-ray System is intended for use on human patients to perform: - Vascular, cardiovascular and neurovascular imaging applications, including diagnostic, interventional and minimally invasive procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTAs, stent placements, embolisations and thrombolysis. - Cardiac imaging applications including diagnostics, interventional and minimally invasive procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology (EP). - Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures. Additionally: - The AlluraClarity Xper FD Series X-ray System is compatible with a hybrid Operating Room. - FD10 is compatible with specified magnetic navigation systems.

Technology:

The AlluraClarity system has the same technological characteristics compared to the predicate device, with the exception of the image processing software. The AlluraClarity system uses the advanced XRES4 (ClarityIQ) noise reduction algorithms to reduce quantum noise in X-ray images.

Non-clinical Performance Data:

The modifications implemented in the AlluraClarity system are limited to the software components of the image processing pipeline. As such, the AlluraClarity System complies with the following international and FDA recognized consensus standard and FDA Guidance Documents with respect to software validation:

- IEC 62304:2006 entitled, "Medical Device Software – Software Life-Cycle Processes."
- FDA Guidance document entitled, "Guidance for the Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.
- FDA Guidance document entitled, "General Principals of software Validation; Final Guidance for Industry and FDA Staff" issued January 11, 2002.

The results of the software validation demonstrate that the software for AlluraClarity System comply with the aforementioned international and FDA recognized consensus standard and FDA Guidance Documents and that the software is adequate for its intended purpose.

Clinical Performance Data:

Clinical performance of the AlluraClarity system is based on retrospective collected and analyzed clinical data.
Retrospective data originated from DICOM structured dose reports and customer satisfaction questionnaires demonstrate the following:

- The AlluraClarity System was successfully utilized during clinical procedures that are covered by the indications for use for both fluroroscopy and acquisitions
- In the completed questionnaires all physicians indicated that the performance of the AlluraClarity System was clinically acceptable.

The results of this analysis demonstrated that physicians were able to perform clinical tasks with the AlluraClarity system on all clinical applications noted in the indications of use of the product, and therefore support a determination of substantial equivalence.

Conclusion:

The AlluraClarity system is substantially equivalent to the predicate devices in terms of indications for use, technology, design, principle of operations and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 28, 2013

Philips Medical Systems Nederland B.V.
% Klien van Dam, Ph.D.
Regulatory Affairs Manager
Veenpluis 4-6
5684-PC, Best
NETHERLANDS

Re: K130638
Trade/Device Name: AlluraClarity Xper FD Series X-ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB
Dated: March 28, 2013
Received: April 01, 2013

Dear Dr. van Dam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130638

Device Name: AlluraClarity Xper FD Series X-ray System

Indications for Use:

The AlluraClarity Xper FD Series C-ray System is intended for use on human patients to perform:

- Vascular, cardiovascular and neurovascular imaging applications, including diagnostic, interventional and minimally invasive procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTAs, stent placements, embolisations and thrombolysis.
- Cardiac imaging applications including diagnostics, interventional and minimally invasive procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology (EP).
- Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.

Additionally:

- The AlluraClarity Xper FD Series X-ray System is compatible with a hybrid Operating Room.
- FD10 is compatible with specified magnetic navigation systems.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health